File Date:	_
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ATTACHMENT #	
EXHIBIT	
ГАВ (DESCRIPTION)	

9. Set the laser system to the desired power output up to a maximum as follows.

Fiber Core Size	9		Minimum Bend Diameter	
(micrometers)				
400 to 600	25Watts	100 Watts	30mm	

Inspection

- 1. With a magnifying eyepiece, microscope or endoscope with operating room video system (minimum magnification 15x), inspect the fiber face at the proximal end of the fiber (at the SMA connector). While inspecting the fiber, slightly change the angle of the fiber face to view a variety of angles at which light strikes the fiber.
- 2. The fiber face should be free of any defects such as chips, cracks, scratches, pits, blemishes or debris. Using the fiber with defects may damage the laser system.

! Caution: If defects exist, do not use the fiber.

- 3. With a magnifying eyepiece, microscope or endoscope with operating room video systems (minimum magnification 15x), inspect the fiber face at the distal end of the fiber. While inspecting the fiber, slightly change the angle of the fiber face to view a variety of angles at which light strikes the fiber.
- 4. Degradation of the fiber face at the distal tip is normal and will occur with use. If pitting, cracks, chips or debris are observed, the fiber should be stripped and cleaved. See instructions that follow.
- 6. Strip and Cleave the Distal Tip of the Fiber

The following tools are recommended for stripping/cleaving the Optical Integrity Laser Fiber. The Supplier is Micro Electronics, Inc., Seekonk, MA 02771

	400mm fiber	600mm fiber
Stripping tool	MS1-27S-31FS	MS1-27S-46FS
Cleaving tool	200/600-C	200/600-C

Note: Verify that the stripping tool corresponds with the fiber size. Read the instructions provided with the stripping tool.

Stripping and Cleaving 400 and 600 mm core fibers

1. Stripping the buffer

Hold the tool in one hand, the fiber in the other. With handles fully expanded insert the fiber in the guide until the fiber end aligns approximately with the tool's 2.5cm (1 inch) rule marking. Squeeze the handles and maintain the closed position while simultaneously withdrawing the fiber from the tool. If the fiber cannot be inserted into the fiber guide, use the scissors to cut approximately 1.2cm (1/2 inch) of the fiber off the distal tip.

2. Cleaving the fiber

With the cleaving tool, gently score the exposed fiber with a straight line perpendicular to the fiber one time approximately 20mm from the distal tip. Do not attempt to cut the fiber with the cleaving tool. Hold the buffered fiber in one hand and the stripped portion between the thumb and index finger of the other hand. Pull the stripped portion away from the buffered section to remove the cleaved tip from the fiber. Do not bend the distal tip while cleaving or break the fiber with a sideways motion. This will result in a poor cleave. Inspect the quality of the cleave as instructed above.

7. Inspecting the quality of the cleaved fiber

- 1. Using a magnifying eyepiece, microscope or endoscope with operating room video system (minimum magnification 15x), inspect the fiber face at the distal end of the fiber to verify a smooth, clean cleave.
- 2. Connect the fiber to the laser and turn on the laser aiming beam.
- 3. Hold the fiber tip approximately one inch from a white surface to examine the pattern of the aiming beam.
- 4. A well-defined circular pattern indicates a good cleave. A slightly oval or distended pattern that remains well defined is an acceptable cleave. A poorly defined pattern with one or more "rays" extending from the central core of the pattern indicates an unacceptable cleave.
- 5. Unacceptable cleaves can result from too much pressure when scoring the fiber core, sideways motion when separating stripped from buffered sections or scoring the tip at an angle other than perpendicular (90 degrees) to the fiber.
- 6. If the cleave is unacceptable, repeat the initial cleaving procedure.

8. How the fiber is Supplied and Stored

- The Optical Integrity Fiber is supplied as EtO sterilized disposable product. Sterility is guaranteed only if the package is not opened, damaged or broken.
- Each package contains 1 Fiber in a dispensing coil and 1 instruction for use booklet.
- Store in a dry, cool place.

Optical Integrity's European Representative is:

0413 European Device Solutions, Inc.

email: TQMUK@aol.com

This symbol means, Caution! The information provided is important and can affect the safety or efficacy of the product.

This symbol means that the product is a single use product not intended for reprocessing or reuse.

This symbol means that the information provided is instructional for the safe and effective use of the product.



BARD | MEDICAL

ESSENTIAL, EFFECTIVE, EFFICIENT.

<u>Home Products Kidney & Stone Management Laser Fibers ENDOBEAM™ Holmium Laser Fibers - Single Use</u>

<u>Prescriptive - More</u>

Prescriptive Information

Indications for Use:

The BARD® ENDOBEAM™ Holmium Laser Fibers are indicated for a variety of surgical uses including open, laparoscopic, or endoscopic ablation, incision, excision, vaporization, and coagulation of soft and cartilaginous tissue and in surgical procedures involving vaporization, ablation and fragmentation of calculi.

The delivery system may be used in surgical specialty procedures for which compatible Holmium and Nd:YAG lasers have received regulatory clearance. Refer to your laser system user manual for complete information regarding applications, contraindications, precautions and warnings when using this fiber.

Contraindications:

- The devices are contraindicated for treatment of patients for whom endoscopic procedures are not recommended.
- · Refer to the laser system manual for contraindications that may be specific to each surgical specialty

Cautions

· Federal (USA) law restricts this device to sale by or on the order of a physician.

Warnings:

- Improper use of the device or use of a damaged device may result in severe eye or tissue damage, accidental laser exposure to the treatment room personnel or patient which may result in severe burns to the user or patient, and fire in the treatment room.
- Baskets, guidewires and other ureteroscopic accessories may be damaged by direct contact with the laser treatment beam.
- Do not bend fiber at sharp angles. If visible light (aiming beam) can be seen leaking from the fiber, fiber
 failure may result when therapeutic energy is applied as the fiber is deflected beyond the optical limits of
 total internal reflection.
- Fiber should not be clamped with forceps or other securing instruments as it may result in fiber damage or breakage.
- Ensure that all procedure room personnel wear appropriate protective eye-wear during the delivery of laser energy. Failure to do so may result in injury.
- For the single-use laser fiber, do not sterilize any portion of the device. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

EXHIBIT

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- The reusable laser fibers must be thoroughly cleaned and sterilized before reuse.
- A tapping noise may indicate fiber misalignment to generator. See Fiber Output Test for additional details and instructions.

Precautions:

- · When removing the fiber from its pouch or tray, secure the distal tip to avoid damage or contamination.
- · Do not apply excessive force to the tip of the fiber as breakage may result.
- Begin lasing at the lowest possible power/energy setting to achieve the desired effect. Use lower power levels and shorter pulses to familiarize yourself with the operation of the BARD® ENDOBEAM™ Holmium Laser Fiber.
- High power/long duration of laser energy while placing the tip in contact with tissue may damage or significantly reduce the life of this product.
- Direct contact by laser beam may cause damage to guidewires, baskets or other ureteroscopic accessories.
- If fiber tip is visibly damaged or requires excessive amounts of energy to affect coagulation or vaporization, discontinue use and replace with a new fiber for optimum results. If desired, strip and cleave the fiber as outlined in the "Instructions for Stripping and Cleaving" and "Fiber Output Test" sections of this IFU.
- DO NOT exceed the recommended power levels when utilizing the BARD® ENDOBEAM™ Holmium Laser Fiber.
- · Check the device for completeness once removed from patient.

Adverse Events:

The potential adverse effects associated with Holmium laser fibers may include but are not limited to:

- Perforation
- Hematoma
- · Vasovagal response
- Infection
- · Thermal damage
- Edema
- · Bleeding
- Discomfort
- Hypertension
- · Delay in healing
- Post-procedure fever and leukocytosis (associated with tissue destruction)

For the latest information, always check the "Instructions for Use" that comes packaged with the product.

This site is intended for healthcare professionals. If you are a patient seeking more information, please consult your healthcare provider.

Training and Education

For additional training and education on a number of topics, visit our **Training Center**

Contact Us

read more

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Please contact your local Bard Medical representative for information about products available in your area.

This site is intended for healthcare professionals. If you are a patient seeking more information, please consult your healthcare provider.

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DuoTome™ SideLite™ Fiber Instruction Guide

Indications for Use

The DuoTome[™] SideLite[™] fiber is compatible with the following lasers:

- VersaPulse® 2.1 Holmium
- VersaPulse Select Holmium
- VersaPulse Select Dual Wavelength
- VersaPulse PowerSuite TM Holmium
- VersaPulse PowerSuite Dual Wavelength

Intended Use

The device is intended for use with the compatible lasers in surgical procedures involving open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue, cartilage, and calculi. For the safe use of the devices, read and comprehend these instructions and the appropriate laser operator manual before use.

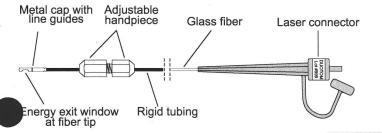
Contraindications

The device is contraindicated for treatment of patients for whom endoscopic procedures are contraindicated. Refer to the laser operator manual for contraindications that may be specific to each surgical specialty.

Device Description

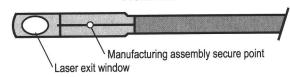
The device is single-use and is supplied EtO-sterilized. It consists of a laser connector, glass fiber, metal cap with line guides, adjustable handpiece, and rigid tubing. The laser connector secures the device to the laser. The glass fiber transmits laser energy from the laser console to the treatment site through the side opening at the fiber tip. Laser energy is delivered at approximately a 70° angle to tissue from the tip of the fiber. The line guides assist with correct positioning of the fiber tip within an endoscope. The adjustable handpiece enables manipulation of the fiber tip at the treatment site. The rigid tubing aids in control of the fiber tip.

CAUTION - U.S. federal law restricts this device to sale by or on the order of a physician.



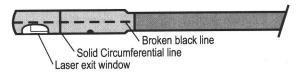
Metal Cap Line Guides

Front view



- Laser energy is emitted from the exit window and distal to the circumferential line.
- The small round opening proximal to the solid circumferential line is a manufacturing assembly securing point.
 This opening should not be confused with the laser energy exit window.

Side view



- Broken black lines: laser energy is emitted at approximately 90° to the broken lines.
- Solid circumferential line: indicates minimum safe retraction distance of the fiber into the endoscope. This line must be visible when the laser is activated to avoid scope damage.

Rear view Solid black line Solid Circumferential line

• Solid black line: laser energy is emitted at approximately 180° to the solid line.



WARNING - In the unlikely event that the metal cap detaches during use, locate the detached metal cap and remove it using forceps. Irrigate area well to remove any debris.



WARNING - Improper use of the device or use of a damaged device may result in severe eye or tissue damage; fire in the treatment room; or accidental laser exposure to the treatment room personnel or patient. Refer to the appropriate laser operator manual for detailed safety information.



WARNING - When using a fiber optic delivery device, always inspect it to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the fiber with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the fiber. A damaged fiber may cause accidental laser exposure, injury or burns to treatment room personnel or patient, and/ or fire in the treatment room.

Precautions

To avoid damage to the fiber:

- Ensure that the scope port is open prior to inserting the fiber into the scope.
- Avoid bending the fiber, particularly when holding the handpiece or manipulating the scope.
- Avoid clamping or clipping any devices such as a hemostat on to the fiber.
- The DuoTome SideLite fiber is designed for use in an aqueous environment only. Do not use the device in air, and do not insert the tip into tissue. Both conditions do not provide an adequate aqueous environment for proper cooling of the tip and will permanently damage the device.

To avoid damage to accessory devices:

 Avoid direct laser beam contact with accessories. Baskets, guide wires, and other ureteroscopic accessories may be damaged.

Potential Complications

General complications associated with holmium and Nd:YAG wavelengths

- The potential complications encountered in endoscopic laser surgery are the same as those normally encountered in conventional endoscopic surgery.
- Acute pain may occur immediately following laser therapy and may persist for as long as 48 hours.
- Immediately following laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment.
- Laser-ablated tissue may become necrotic or infected after treatment. If a question of infection exists, appropriate treatment should be carried out.

The following complications are serious and could result in death:

- Patients may experience bleeding at the site of laser therapy. Post-treatment hematocrits are recommended to identify this potential complication.
- Sepsis can result from performing any surgical procedure.
 If a question of sepsis exists, appropriate evaluations should be made.
- Perforation may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.

Pre-Operative Instructions

Use the following technique to verify package integrity and safe use of the device.



CAUTION - Careful handling of the glass fiber during setup is important to prevent fiber damage. Fiber damage may impact fiber performance.

Circulating nurse:

- 1. Ensure that the sterile packaging is not torn or punctured. If necessary, return the device to the supplier for replacement.
- 2. Open the outer pouch.

Scrub nurse:

- 3. Take the sterile inner pouch, and place it inside the sterile field.
- 4. Open the sterile pouch, and remove the device.
- 5. Hand the laser connector to the circulating nurse.

Circulating nurse:

6. Hold the laser connector and remove the protective cap. Do not hold the rubber strain relief or the fiber.





- 7. Insert the laser connector into the fiber receptacle on the front of the laser console, and finger-tighten.
- 8. Turn on the laser, and set the aiming beam to high intensity, as instructed in the laser operator manual.

Scrub nurse:

- 9. Inspect the fiber for kinks, punctures, fractures, or other damage. If the fiber appears damaged, do not use the device; return it to the supplier for replacement.
- 10. Hold a nonreflective surface in front of the side opening at the fiber tip, and ensure that a circular red spot appears. If the spot is weak or not visible, discard the device or return it to the supplier for replacement.

Circulating nurse:

11. Set the laser treatment parameters, as instructed in the laser operator manual.

Intra-Operative Instructions



PRECAUTION - In order to achieve optimum fiber efficiency when treating with both wavelengths during the same procedure, use Nd:YAG prior to using holmium. Throughout a typical procedure, the delivery efficiency of this device is >60% of the energy setting on the control screen.

- 1. Move the handpiece to the desired position by loosening the sections until the entire handpiece slides easily along the rigid tubing.
- 2. Fasten the handpiece in place by tightening the two sections together until the handpiece sits securely on the rigid tubing. If handpiece is not securely attached to rigid tubing, fasten the handpiece again.
- 3. Position the aiming beam on the target tissue, cartilage, or calculi.



PRECAUTION - Do not bury the fiber in tissue. This will cause the fiber to overheat and permanently damage the device.



PRECAUTION - The energy exit window should be directed toward tissue when the laser is activated. If the exit window is visible on the video screen, the laser energy is not being used most efficiently. The solid black line should be visible on the video screen.

- 4. Ensure that the circumferential line guide at the fiber tip is visible on the video screen and exits the endoscope.
 - PRECAUTION **Never** activate the laser if the fiber tip is not extended beyond the end of the scope and the circumferential line is not visible.
- 5. Place the laser in ready mode.
- 6. Press the footswitch to deliver the laser energy.



PRECAUTION - Laser fibers are consumable devices and performance degrades with use. Various factors influence fiber life and degradation, such as tissue composition, tissue mass and surgical technique. Total energy transmission through the fiber will vary depending upon these factors.

Fiber Degradation Indicators

- Aiming beam fades or disperses
- Ablation rate diminishes
- Metal cap distorts, discolors or indents

These changes do not require discontinuing of use, but do indicate that the fiber is becoming less efficient.

In the final phase of degradation, white flashes of light may appear at the tip, the aiming beam may exit at a point other than the energy exit window or a sudden increase in bubbles at the metal cap may occur. Discontinue use and replace with a new fiber to complete the procedure, if necessary. The use of more than one fiber in some cases may be necessary, particularly when treating larger glands.

Post-Operative Instructions

The DuoTome SideLite fiber is a single-use device. **Do not** reuse or resterilize the fiber. After use, dispose of the device properly.

Storing the Device

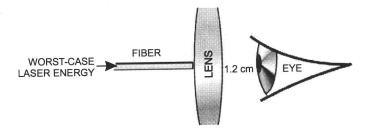
Store at room temperature. Do not expose to organic solvents, ionizing radiation, or ultraviolet light. Rotate inventory so that devices are used prior to the expiration date on package label.

Laser Safety Eyewear

The facility Laser Safety Officer should determine the need for safety eyewear based on the optical parameters outlined in the appropriate laser operator manual. For detailed laser safety eyewear information, carefully read the laser operator manual before use.

All personnel within the NOHD are considered to be within the controlled area of the treatment room and shall wear eye protection with the minimum OD specified in the following table:

Wavelength	MPE	NOHD	Min. OD
Ho:YAG (2.1 μm)	2 mJ/cm ²	1.1 m	4.0
Nd:YAG (1.06 μm)	17 μJ/cm ²	9.8 m	5.4



Warranty Information

Lumenis warrants this device to be free from defects in materials and workmanship, and to perform in the manner and under the conditions specified in this instruction guide. The customer is entitled to a replacement or credit for a device that is defective upon initial inspection of the sterile packaging or upon first use when properly connected to the laser. The defective device must be returned to the company from which it was purchased.

Decontamination of Returned Equipment

To comply with United States postal and transportation law, quipment shipped to the supplier's US offices for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for use as a "Hospital Disinfectant". To ensure that all equipment has been properly decontaminated, a signed Decontamination Certificate (provided at the back of the laser operator manual) must be enclosed in the package, or the supplier will assume that the product is contaminated and will assess the customer with cleaning costs. Any decontamination inquiries should be directed to the supplier's US service offices.



NOTE - When returning products to the supplier, please note the manufacturing lot number located on the device.

Location of Regulatory and Other System Labels

As required by national and international regulatory agencies, appropriate warning labels are located on the outer packaging.



Read and comprehend operator manual before use



CE compliance

REF

Part number

LOT

Lot number



2007-02-02

Expiration date, in yyyy-mm-dd format

STERILE EO

EtO sterilized



Single use only

CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

U.S. sales restriction label

Specifications

Specifications subject to change without notice.

	Holmium		Nd:YAG	
Delivery Device Specifications	Air	Water	Air	Water
Compatible Wavelengths	N .	1		1
Total Length	3 m (9.8 ft)			
Maximum Output Energy	4.0 J			
Maximum Output Power	100 W			
Fiber Core Diameter	550 μm			
Maximum Outer Diameter	2.4 mm			
Minimum Working Channel Diameter	7.5 Fr			

At any energy setting, your repetition rate should be adjusted so as not to exceed the power specification listed in the above table.

This product is latex free.







PB-1007740, Revision A, May 2007

European Regulatory Representative:

Lumenis (Germany) GmbH Heinrich-Hertz-Strasse 3 D-63303 Dreieich, Germany +49.6103.8335.0

Manufactured by Lumenis Ltd.

P.O.Box 240, Yokneam 20692, Israel +972.4.959.9000

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- PHYSICIAN TIME
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Help

CM SUBSCRIPTIONS ▼

Overview

General Information

36478 - ENDVNS ABLTN THRPY OF INCMPTNT VN, EXTRMTY, INCLSV OF ALL IMGNG GDNC AND MNTRNG, PRCTNS, LSR

Long Descriptor

Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated

26

TC

	Global
Work RVU/Base Units:	6.72
Non Facility Practice Expense RVU:	34.53
Facility Practice Expense RVU:	2.61
Professional Liability Insurance RVU:	1.32
Non Facility Total RVU:	42.57
Facility Total RVU:	10.65
Medicare Non Facility National Payment:	\$1,564.17
Medicare Facility National Payment:	\$422.28
Medicare Status*:	A
Medicare Policy Indicators*:	ABM

* Please refer to the help file for definitions and explanations.

EXHIBIT

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CPT Publication/Review Date: 2005

Global Period:

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Overview

General Information

36479 - ENDVNS ABLTN THRPY OF INCMPTNT VN, EXTRMTY, INCLSV OF ALL IMGNG GDNC AND MNTRNG, PRCTNS, LSR SCND AND SBSQNT VNS TRTD IN SNGL EXTRMTY, ECH THRGH SPRT ACCSS STS (LST SPRTLY IN

Long Descriptor

second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

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8.39	
1.22	
0.65	
12.42	
5.25	
\$422.75	
\$178.70	
A	
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	3.38 8.39 1.22 0.65 12.42 5.25 \$422.75 \$178.70 A

* Please refer to the help file for definitions and explanations.

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Term	Definition
Medical Social Services	Services to help you with social and emotional concerns related to your illness. This might include counseling or help in finding resources in your community.
Medical Supplies	Essential items that the home health team uses to conduct home visits or to carry out services the physician has ordered to treat or diagnose a patient's illness or injury. Examples include: cotton balls, adhesive and paper tape, thermometers, dressings for wound care, sterile gloves, catheters, and syringes. The home health agency provides these supplies for their use with the patient.
Medically Necessary	Services or supplies that are needed for the diagnosis or treatment of your medical condition and meet accepted standards of medical practice.
Medicare- covered Home Health Care Services	Medicare Parts A and B cover part-time or intermittent skilled nursing care, physical therapy, occupational therapy, speech therapy, home health aide services, medical services, durable medical equipment (such as wheelchairs, hospital beds, oxygen, and walkers) and medical supplies, and other services. Note: You must meet certain conditions.
	The list of services is obtained from the Quality Information Evaluation System (QIES) database maintained by the State Survey Agency and updated monthly.
	The agency may offer additional services so it is important to check with the agency for the most current information.

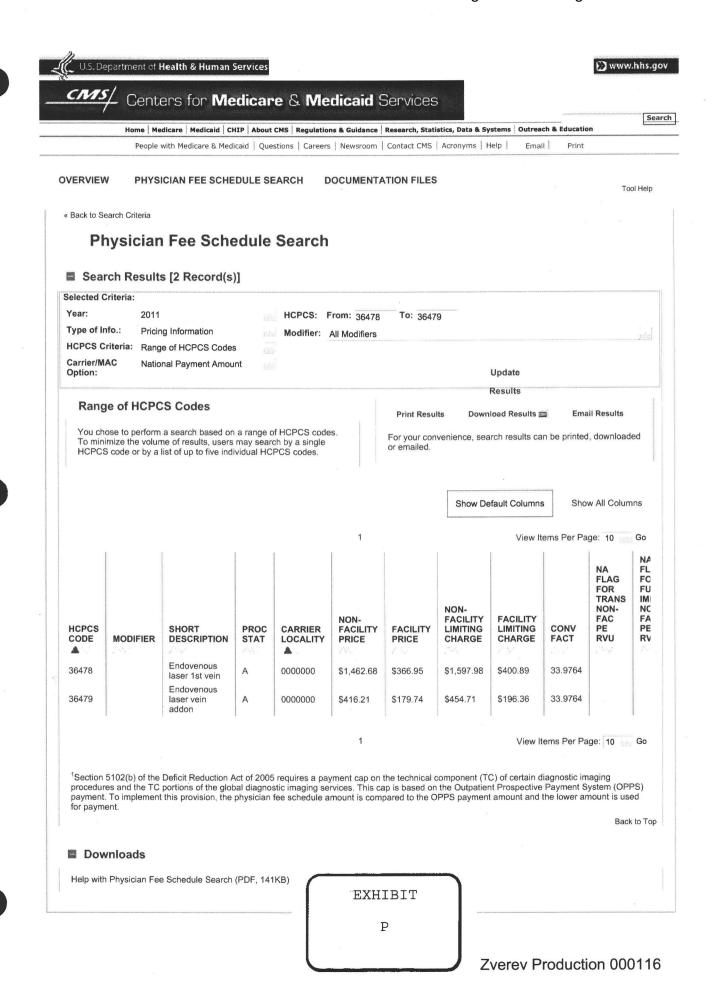
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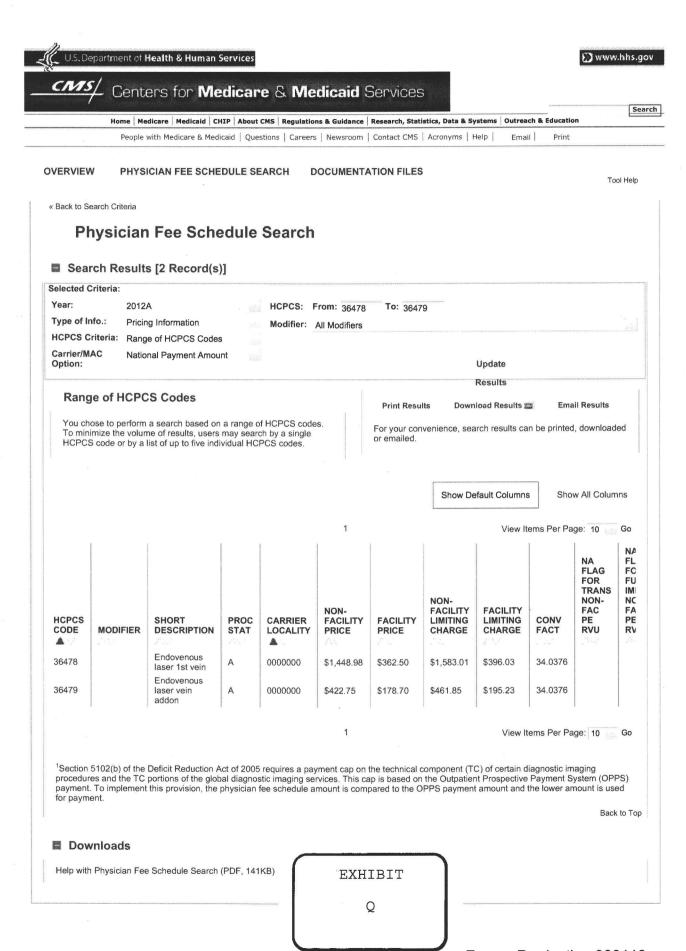
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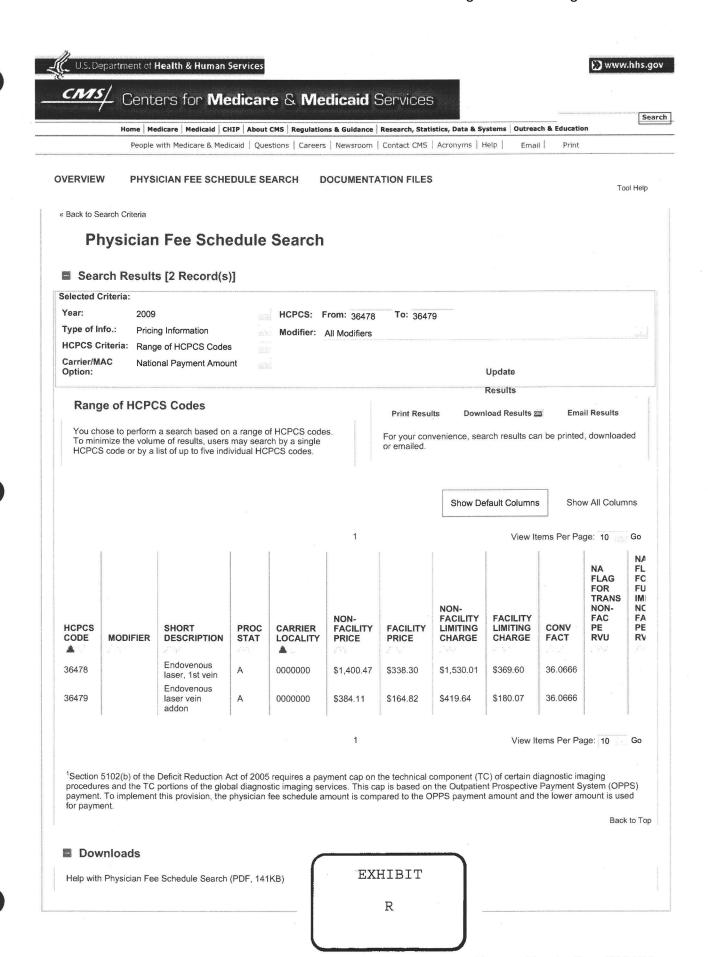
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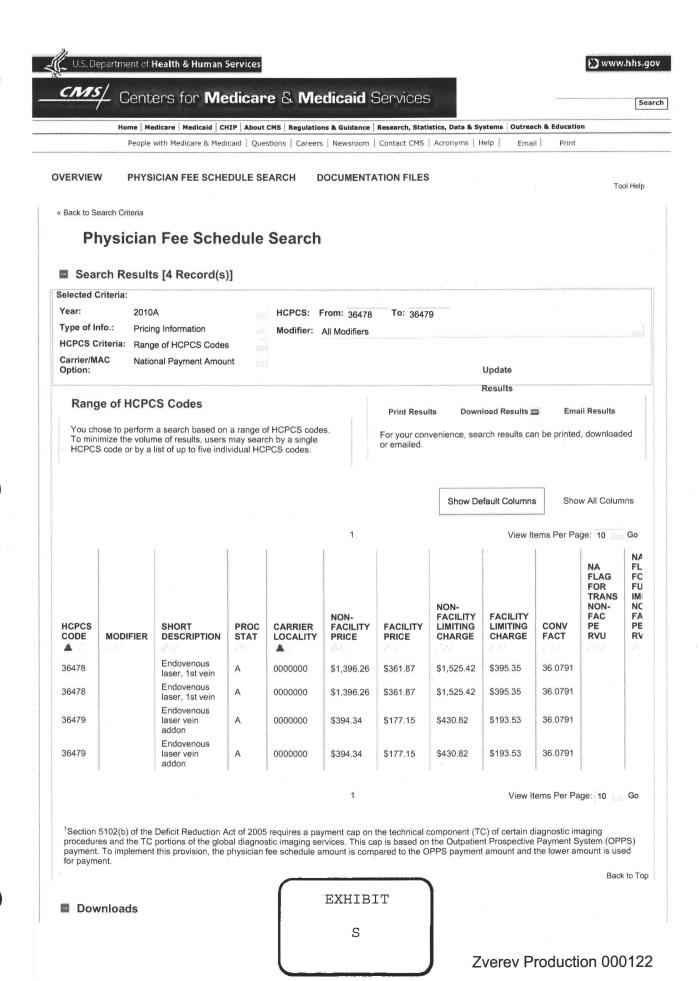


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http://www.cms.gov/apps/physician-fee-scnedule/searcn/searcn-results.aspx?Y=4&T=0&...

10/5/2012

Help with Physician Fee Schedule Search (PDF, 141KB)

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